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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD. and ACTELION CLINICAL RESEARCH, INC., Plaintiffs,	)	
v.	)	Case No. 1:12-cv-05743-NLH-AMD
APOTEX INC., APOTEX CORP., ROXANE LABORATORIES, INC., and ACTAVIS ELIZABETH LLC, Defendants.	)	

REPLY MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR JUDGMENT ON THE PLEADINGS AND TO DISMISS THE COUNTERCLAIMS

Motion Day: April 1, 2013

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INTRODUCTION AND SUMMARY OF ARGUMENT

Actelion's motion presents a straightforward question of law: Is Actelion entitled to choose with whom it does business? Defendants' attempt to confuse this issue is a red herring. They claim to have alleged a "scheme" involving Actelion's design and use of the FDA-approved REMS program, but this supposed scheme is reflected nowhere in their counterclaims. In any event, Actelion's distribution programs for Tracleer and Zavesca were submitted to, reviewed by, and approved by, the FDA, and are therefore protected from antitrust attack under the First Amendment to the Constitution of the United States and the *Noerr-Pennington* doctrine.

The only supposedly "exclusionary" act defendants actually allege is Actelion's refusal to sell them samples of Tracleer and Zavesca. However, more than 100 pages of briefing by defendants and their *amici* have not obscured these simple and undisputed facts: (1) Actelion has never sold Tracleer to any defendant and does not wish to do so; (2) Actelion has never sold Zavesca to Roxane and does not wish to do so. No law—not Hatch-Waxman, not the Sherman Act, and not any other existing Act of Congress—obligates Actelion to do business with defendants where it has never done so and does not wish to do so.[1]

The Supreme Court has been clear on this: Actelion has the right to decide with whom to deal absent a prior, voluntary course of dealing. This common law right is buttressed by Actelion's patent rights, which include the right not to sell its products, and to decide to whom to sell them. Defendants' repeated invocation of the Bolar Amendment is inapposite; nothing in the Bolar Amendment alters these core patent rights. In fact, Congress's decision to circumscribe

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[1] Johnson Matthey Inc. moved to intervene in this matter the day before this brief was filed. To the extent Johnson Matthey's motion is granted, Actelion intends its motion for judgment on the pleadings and to dismiss the counterclaims to apply to Johnson Matthey.

branded companies' patent rights in such a narrow and precise manner illustrates that it did not intend to abrogate entirely the fundamental right of a patent holder not to sell its product.

Critically, defendants ignore the reality that the relief they seek would necessarily embroil Actelion and the Court in on-going monitoring of defendants' bioequivalence testing. This is not empty rhetoric. Defendants admit that Tracleer and Zavesca present serious patient safety issues, including liver damage, birth defects, and neuropathy, but blithely promise that "they can handle it." Actelion is not required to, and cannot, simply accept their say-so. Nor is Actelion obligated to invest the resources to confirm each defendant's promise and then to monitor each defendant as it administers ***Actelion's*** drugs to patients.

No court has ever required a pharmaceutical manufacturer to sell an indisputably risky drug to a rival, and then to monitor the rival's administration of the drug to patients. Such a measure would be extraordinary. Moreover, it would also thrust the Court into a supervisory, quasi-regulatory role with respect to a host of issues likely to arise in connection with these monitoring efforts—precisely the type of role that the Supreme Court has directed district courts to avoid in refusal to deal cases.

Defendants and *amici* argue that Actelion's position disturbs the balance struck by Congress in the Hatch-Waxman amendments. Congress, however, twice considered and rejected proposed legislation that would have created the very obligation defendants seek to impose on Actelion. Congress' choice not to enact such legislation reflects its judgment regarding the appropriate balance among the various interests at stake, including the protection of intellectual property, the branded companies' right to choose with whom to do business, potential liability

issues, promoting competition, and other related issues. It is the defendants—by urging this Court do something Congress did not—who seek to upset the balance struck by Congress.

Finally, the restrictions in Actelion's distribution agreements are not subject to Section 1 scrutiny, ***not*** because distribution agreements are somehow exempt from the Sherman Act, but because the restrictions are a condition imposed by Actelion to insure patient safety and to comply with the FDA-reviewed and approved distribution programs. Defendants have pled no fact, which, if true, would demonstrate that these restrictions are any broader than required for these purposes. That, in itself, warrants dismissal of Roxane's claim.

For the reasons explained below and in Actelion's opening Memorandum of Law, Actelion respectfully requests that the Court enter a declaratory judgment that it is under no obligation to deal with the defendants and dismiss the counterclaims with prejudice.

LEGAL ARGUMENT

I. THIS CASE CONCERNS A SIMPLE REFUSAL TO DEAL, NOTHING MORE.

Actelion seeks a declaration that it may, as a matter of law, unilaterally refuse to sell its drug products to the defendants. This is not a controversial legal proposition. *See United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). Perhaps recognizing this, defendants assert for the first time in their opposition that Actelion has implemented a "scheme" involving both a refusal to deal and the design of "intentionally overbroad" REMS and restricted distribution programs. Neither the "scheme" nor any ***facts*** supporting it appear in the counterclaims.

Defendants contend that Actelion designed "over-restrictive" programs that prevent only generic competitors from obtaining Tracleer and Zavesca. (Opp. at 23, 24 (Doc. 58)). Defendants have not, however, alleged a single fact showing that any element of the FDA-

reviewed and approved REMS or restricted distribution program goes beyond what is necessary to protect patient safety or is being used for any purpose other than patient safety.[2] Defendants' conclusory assertions of a "scheme," without any supporting factual allegations, cannot survive a motion to dismiss. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("[A] complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'") (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Phillips v. County of Allegheny*, 515 F.3d 224, 232 (3d Cir. 2008).

Moreover, defendants' new theory is legally flawed because it rests on submissions to, and decisions by, the FDA related to the distribution of Tracleer and Zavesca. Actelion was required to submit the details of the REMS and restricted distribution program to the FDA for approval. Actelion's submissions to the FDA constitute petitioning, which is immune from antitrust liability under the First Amendment and the *Noerr-Pennington* doctrine. The *Noerr-Pennington* doctrine precludes antitrust claims predicated on the petitioning itself or government actions that result from the petition. *Prof'l Real Estate Investors v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993); *Mass. Sch. of Law at Andover, Inc. v. Am. Bar Ass'n*, 107 F.3d 1026 (3d Cir. 1997). This immunity extends to administrative petitioning, such as requests to the FDA

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[2] The counterclaim paragraphs cited by defendants as the source for their "scheme" do not allege any facts concerning the design of the REMS program. Rather, the allegations of the cited paragraphs are based on "Actelion's ***refusal to supply***" samples (Actavis Countercl. ¶ 36) (emphasis added); state that Actelion was "***refusing to sell***" samples (Apotex Countercl. ¶ 63) (emphasis added); describe a defendant's efforts to purchase samples from Actelion and Actelion's "persistent ***refusal to sell*** samples" (Apotex Countercl. ¶¶ 54-59) (emphasis added); and state that Actelion is "***unwilling to sell***" products (Roxane Countercl. ¶ 85) (emphasis added). Defendants cite to several additional paragraphs, but those paragraphs merely state broad legal conclusions and conclusory allegations rather than facts. (*See* Roxane Countercl. ¶¶ 34, 105, 126).

for approval of a restricted distribution program and the government action resulting from such petitioning. *See In re Wellbutrin XL Antitrust Litig.*, No. 08-2431, 2012 WL 1657734 (E.D. Pa. May 11, 2012).

Defendants' new "scheme" theory ignores that the law required Actelion to submit its distribution programs to the FDA for its review and approval and that, upon FDA approval, Actelion was required to comply with the programs. (*See* Actelion Br. (Doc. 44.1) at Ex. B (Tracleer Approval Letter) & Ex. D (Zavesca Medical Review.)) Actelion's design of the distribution programs, submissions to the FDA, and Actelion's subsequent implementation of the FDA-approved programs falls squarely within the zone of petitioning activity protected from antitrust challenge under the *Noerr-Pennington* doctrine. The FDA decides when REMS, or other restricted distribution programs, are required and the FDA reviews and approves the specifics of those programs. Any claim by defendants based on distribution restrictions arises directly from the FDA's actions following Actelion's petitioning activity, and cannot be maintained against Actelion. *See Armstrong Surgical Ctr., Inc. v. Armstrong Cnty. Mem'l Hosp.*, 185 F.3d 154, 160 (3d Cir. 1999) (dismissing claim where alleged injury was the result of government action that followed petitioning); *Bristol-Myers Squibb Co. v. Ivax Corp.*, 77 F. Supp. 2d 606, 612 (D.N.J. 2000) (same). Although the defendants argue that the FDA does not review REMS programs for competition law purposes, *Noerr-Pennington* protects petitioning activity before any government agency, regardless of whether that agency applies competition law principles in its review. *See, e.g.*, *Armstrong Surgical Ctr.*, 185 F.3d 154 (petition to state Department of Health); *Coastal States Mktg., Inc. v. Hunt*, 694 F.2d 1358 (5th Cir. 1983) (petition to foreign government); *Bristol-Myers Squibb*, 77 F. Supp. 2d 606 (D.N.J. 2000)

(petition to FDA for orphan drug status); *Lampley v. Bridgestone Firestone, Inc.*, No. 90-A-907, 1992 WL 12666661 (M.D. Ala. Mar. 31, 1992) (petition for OSHA regulations).

In short, defendants' effort to make this dispute something other than what it is—a challenge to Actelion's right to choose whether to do business with defendants—is unavailing. The facts material to that question are not in dispute: Actelion markets Tracleer and Zavesca through a U.S. affiliate; Tracleer and Zavesca are patent-protected; Tracleer and Zavesca pose risks of serious side effects; Tracleer is subject to a REMS; Zavesca is subject to restricted distribution; each defendant tried to buy samples of Tracleer from Actelion for bioequivalence testing; Roxane tried to buy samples of Zavesca from Actelion for bioequivalence testing; Actelion refused to sell samples to defendants; and Actelion has never sold Tracleer or Zavesca to any defendant. (Actelion Br. at 9, 10.) There are no other well-pled material facts.

II. ACTELION HAS NO DUTY TO DEAL WITH DEFENDANTS.

The Supreme Court, and numerous lower courts, have already defined the limited circumstances in which a unilateral refusal to deal might give rise to antitrust liability. Those circumstances are not present here, and Actelion has no duty to deal with defendants.

Defendants' reliance on Third Circuit cases involving alleged exclusionary conduct other than unilateral refusals to deal is inapposite and the principles articulated in those cases do not govern here. This case does not involve an abuse of the standard setting process, as in *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297 (3d Cir. 2007), bundled rebates or cash incentives for exclusivity, as in *LePage's, Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003), or exclusive dealing contracts, as in *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254 (3d Cir. 2012).

The defendants argue that these cases are relevant because the concept of "exclusionary conduct" is inherently flexible. As shown above, however, there is nothing unusual or novel about the conduct at issue here—a straightforward refusal to deal. Because the law on unilateral refusals to deal is both well-settled and directly on point, there is no need to seek guidance from cases dealing with standard setting, bundled rebates, and exclusive dealing contracts.

A. *Trinko* Establishes That a Voluntary Prior Course of Dealing is a Prerequisite to Defendants' Counterclaims.

It is undisputed that Actelion has never sold Tracleer or Zavesca to any of the defendants.[3] Under *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004), that is dispositive. (*See* Actelion Br. at 13-14.) In *Trinko*, the Supreme Court recognized a single exception to the right of a firm, acting unilaterally, to refuse to deal with a rival—the *Aspen Skiing* exception, which may arise where a party ceases a voluntary, prior course of dealing. 540 U.S. at 409 (citing *Aspen Skiing v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985)). The Court in *Trinko* also emphasized that this "limited exception" was "at or near the outer boundary of § 2 liability." *Id.*

Defendants argue that Actelion's reading of *Trinko* is "flawed" and that a prior course of dealing is not a prerequisite. (Opp. at 34.) Defendants rely primarily—and mistakenly—on *Helicopter Transport Services, Inc. v. Erickson Air-Crane Inc.*, No. CV-06-3077, 2008 WL

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[3] Defendants argue that Actelion provided Tracleer and Zavesca samples to third parties for clinical studies unrelated to the submission of any ANDAs. (Opp. at 37.) Even assuming the truth of defendants' allegations in this regard, they are irrelevant to Actelion's prior history of dealing with Apotex, Roxane, and Actavis. The allegation that Actelion provided Tracleer or Zavesca to others for altogether different purposes does not create an obligation for Actelion to provide Tracleer or Zavesca to the generic defendants for the entirely different purpose of replicating them.

151833 (D. Or. Jan. 14, 2008). In that case, Helicopter Transport Services, Inc. ("HTS") alleged that it was a third party beneficiary to a contract under which Erickson Air-Crane ("Erickson") was obligated to supply parts for helicopters. *Id.* at *1. HTS alleged that Erickson refused to sell parts for a particular helicopter model so that it could coerce owners of that model to purchase Erickson's conversion service. *Id.* at *4. Contrary to defendants' assertion, however, *Helicopter Transport Services* did involve a prior course of dealing: HTS, as third-party beneficiary, stood in the shoes of one of the contracting parties.

Even if that were not the case, shortly after the district court decided *Helicopter Transport*, its Court of Appeals addressed the issue in an unrelated case and directly held that a prior course of dealing was required to state a claim based on a unilateral refusal to deal. In *LiveUniverse, Inc. v. MySpace, Inc.*, the Ninth Circuit stated: "[Plaintiff] contends a refusal-to-deal claim does not require an 'affirmative decision or agreement to cooperate' between competitors. [Plaintiff] is mistaken." 304 F. App'x 554, 556 (9th Cir. 2008). The court explained that an antitrust claim based on a refusal to deal "requires, *inter alia*, 'the unilateral termination of a voluntary and profitable course of dealing.'" *Id.* (quoting *MetroNet Servs. Corp. v. Qwest Corp.*, 383 F.3d 1124, 1132 (9th Cir. 2004)).

In its *amicus* brief, the FTC also argues that a prior course of dealing is not required. (*See* FTC Br. at 12-13.) The FTC relies primarily—and mistakenly—on the Tenth Circuit's decision in *Christy Sports, LLC v. Deer Valley Resort Co.*, 555 F.3d 1188 (10th Cir. 2009).[4]

[4] The FTC also argues that the Supreme Court's decision in *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973), is applicable here. It is not. *Otter Tail* involved the refusal of a monopolist to sell or otherwise provide energy so that it could prevent competitors' entry in the downstream market. Here, there is no question of the foreclosure of a downstream market. The generics are seeking to copy Actelion's products so that they

That decision supports ***Actelion's*** position. In *Christy Sports*, the court stated that the "key fact" in *Aspen Skiing* was the termination of a prior, profitable relationship, and, finding no prior, profitable relationship in the case before it, the court affirmed dismissal of the claim. *Id.* at 1197. The Tenth Circuit reinforced this view in a later decision, *Four Corners Nephrology Associates, P.C. v. Mercy Medical Center of Durango*, 582 F.3d 1216, 1224-25 (10th Cir. 2009), holding that *Aspen Skiing* controls "***only***" where a voluntary course of dealing was unilaterally terminated and where the termination suggests an anticompetitive end.

The Ninth Circuit's decision in *LiveUniverse* and the Tenth Circuit's decision in *Four Corners Nephrology* join numerous other appellate and district court decisions that have determined that *Trinko* requires a prior, voluntary course of dealing in order to state a claim. *See, e.g.*, *In re Elevator Antitrust Litig.*, 502 F.3d 47, 53-54 (2d Cir. 2007) (stating that a case in which a monopolist seeks to terminate a prior course of dealing with a competitor is the "sole exception" to the right to refuse to deal); *Covad Commc'ns Co. v. BellSouth Corp.*, 374 F.3d 1044, 1049 (11th Cir. 2004) ("*Trinko* now effectively makes the unilateral termination of a voluntary course of dealing a requirement for a valid refusal-to-deal claim under *Aspen*."); *Apple iPod iTunes Antitrust Litig.*, 796 F. Supp. 2d 1137, 1145 (N.D. Cal. 2011) (granting summary judgment due to absence of a prior course of dealing); *Compliance Mktg., Inc. v. Drugtest, Inc.*, No. 09-cv-01241, 2010 WL 1416823, at *15 (D. Colo. Apr. 7, 2010) ("Plaintiffs do not allege any prior course of dealing between themselves and [defendant]. [Defendant] has, therefore, no duty to deal."); *Precision CPAP, Inc. v. Jackson Hosp.*, No. 2:05-cv-1096, 2010 WL 797170, at *11 (M.D. Ala. Mar. 8, 2010) ("This *Aspen Skiing* exception applies only if: (a) the defendant

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can compete in the same market. There is no precedent for imposing an affirmative duty to deal in circumstances such as this.

engaged in a prior course of dealing with its rival; *and* (b) the unilateral termination of a voluntary (and thus presumably profitable) course of dealing suggested a willingness to forsake short-term profits to achieve an anticompetitive end." (internal quotation marks omitted)); *RxUSA Wholesale, Inc. v. Alcon Labs., Inc.*, 661 F. Supp. 2d 218, 228 (E.D.N.Y. 2009) (dismissing § 2 claim because defendants never voluntarily did business with plaintiff).

This litany of cases also shows that *Trinko* is not limited to the telecommunications industry, as defendants urge. (*See* Opp. at 28-33.) Defendants assert that *Trinko* is inapplicable here because there is not a separate "legal framework that affirmatively protects the competitive process." (Opp. at 30, 33.) Defendants cite no authority for this proposition. On the contrary, *Trinko* has routinely been applied to industries that do not have a separate "legal framework that affirmatively protects the competitive process." *See, e.g.*, *LiveUniverse*, 304 F. App'x 554 (internet); *Four Corners Nephrology*, 582 F.3d 1216 (physician services); *In re Elevator Antitrust Litig.*, 502 F.3d 47 (elevators and elevator services); *Compliance Mktg.*, 2010 WL 1416823 (pre-employment testing services); *RxUSA Wholesale*, 661 F. Supp. 2d 218 (wholesale pharmaceuticals).

B. Undisputed Safety Risks Make a Forced Sale Inappropriate Under *Trinko*.

A forced sale will necessarily involve far more than the "one time purchase" suggested by the defendants. They concede that Tracleer and Zavesca can cause very serious side effects, including liver damage, birth defects, and neuropathy.[5] Their answer is to assure Actelion and the Court that they can handle these safety issues.

[5] Risks include elevations in liver enzymes, potential liver failure, major birth defects, pulmonary edema, and changes in blood counts. *See* Tracleer REMS at 17-19.

Given the potential liability and reputational risks—in addition to its obligations under the FDA-reviewed and approved REMS and restricted distribution program—Actelion should not, and cannot, just accept defendants' assurances that they can handle the safety issues that are associated with Tracleer and Zavesca. If it were forced to sell Tracleer and Zavesca to the defendants, Actelion would be required to verify each individual defendant's ability to administer the drugs safely, examine their protocol for doing so, and monitor their ongoing use of the drugs during the bioequivalence testing.[6] Actelion would be required under Tracleer's REMS to monitor and track to whom the drug was administered, how much of the product was given to the patient, when the drug was dispensed, whether the required patient counseling was performed, and whether required liver and pregnancy tests were completed. (*See* Tracleer REMS at 3-6.) These monitoring efforts would need to be tailored to the testing protocols implemented by each individual defendant.

Moreover, a forced sale would thrust the Court into precisely the type of supervisory, quasi-regulatory role that the Supreme Court warned district courts against in *Trinko*. As the Court explained, "Enforced sharing also requires antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they are ill suited." *Trinko*, 540 U.S. at 408. Here, the "other terms of dealing" would include the process

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[6] As the manufacturer of Tracleer and Zavesca, Actelion is responsible for insuring the safety of patients who use these products. For this reason, Actelion, as required by Tracleer's REMS, distributes Tracleer "through a restricted distribution network," and implements "ongoing, comprehensive" programs to track that the necessary patient testing is performed, and to track adverse events and fetal exposure, to name only a few of the REMS requirements. (Tracleer Approval Letter at 2; *see also* Actelion Br., Ex. C (Tracleer REMS)). Actelion's ongoing duty to safely provide Zavesca similarly requires that distribution be restricted as agreed in consultation with the FDA prior to Zavesca's approval. (Zavesca Medical Review at 1-2) (requiring ongoing restricted distribution to manage the risk/benefit ratio).

for monitoring the defendants' use of Actelion's products to insure patient safety during the bioequivalence testing, precisely the type of regulatory function that the Supreme Court directed district courts to avoid. *Id.* at 415.

A forced sale, and the associated monitoring efforts, would likely give rise to a myriad of questions and potential conflicts requiring judicial intervention. Such questions could arise in connection with a number of issues, including (1) the information to be provided to Actelion regarding the defendants' testing protocols and how Actelion's drugs will be administered to patients, (2) the nature of Actelion's involvement in the testing process, and (3) the defendants' compliance with the safeguards required under the REMS and restricted distribution programs. For example, if a dispute arose regarding whether defendants must provide certain patient information to Actelion, or, similarly, whether patients were being adequately counseled or monitored, Actelion would need to ask this Court to intervene.

These concerns are real. In addition to compliance with the FDA-approved REMS and restricted distribution programs, the sale of Tracleer and Zavesca creates potential liability and reputational risks for Actelion. Defendants' assurances that they can handle the safety issues ring particularly hollow in light of the history of generic manufacturers shifting liability risks to branded companies. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (because a generic version of a drug is the "same as" the branded drug, a generic manufacturer cannot be held liable for claims relating to product labeling, and all risk of liability for such claims falls on the branded company); *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30 (1st Cir. 2012), *cert. granted*, 133 S. Ct. 694 (generic manufacturers seeking to insulate themselves from liability based on alleged design defects of a drug product). Moreover, *Mensing* and *Bartlett* involved liability issues

arising from the marketing of a generic version of the branded products. The stakes for Actelion are even greater here because the defendants will be administering drug products manufactured by Actelion.

Congress recognized the potential liability risks that would be imposed on companies like Actelion if forced to deal with potential generic rivals. The version of the Food and Drug Administration Safety and Innovation Act that passed the Senate contained proposed language allowing (and perhaps requiring) branded companies to sell samples of REMS-covered drugs to potential generic rivals. (*See* Actelion Br. at 20.) That version also included language shielding the branded company from liability "for any claim arising out of [the generic's] provision or testing of a drug obtained under this subsection, including a claim arising out of failure of [the generic] to follow adequate safeguards to ensure safe use of the drug." (*See* S. 2516, 112th Cong. § 1131 (May 7, 2012), attached as Ex. A.) Although Congress did not adopt legislation requiring the sale of samples, rendering the liability shield unnecessary, the proposed provisions reflect recognition that forcing a branded company to sell product to a generic would potentially give rise to very real liability risks. This is precisely why such a drastic change in existing law is a matter for Congress, and not the courts.

C. The Essential Facilities Doctrine is Inapplicable, Even If Still Valid.

1. The Doctrine Does Not Apply in These Circumstances.

The continued vitality of the essential facilities doctrine is in doubt after *Trinko*. (Actelion Br. at 14-15.) Defendants' suggestion that the doctrine has merely been questioned "by some law professors" (Opp. at 39) ignores the courts, including one in this Circuit, that have questioned the doctrine's ongoing validity. *See Four Corners Nephrology*, 582 F.3d at 1222

(recognizing the Supreme Court's "skepticism" about the doctrine); *Pocono Invitational Sports Camp, Inc. v. Nat'l Collegiate Athletic Ass'n*, 317 F. Supp. 2d 569, 587 n.23 (E.D. Pa. 2004) (stating that *Trinko* called the viability of the essential facilities doctrine into question except in the most extreme cases).

None of the post-*Trinko* cases defendants cite actually held that the doctrine applied. *See Morris Commc'ns Corp. v. PGA Tour, Inc.,* 364 F.3d 1288 (11th Cir. 2004) (stating, without analysis or application, that the essential facilities doctrine was a theory); *MetroNet Servs. Corp. v. Qwest Corp.*, 383 F.3d 1124 (9th Cir. 2004) (rejecting essential facilities claim). In *Lannett Co. v. Celgene Corp.*, No. 2:08-cv-03920 (E.D. Pa. June 18, 2010), the court's one sentence order denying the motion to dismiss did not mention the doctrine. *See Plocica v. NYLCare of Tex., Inc.*, 43 F. Supp. 2d 658, 664 n.4 (N.D. Tex. 1999) (finding that court's five line order without legal reasoning or explanation of decision was not persuasive).

Putting aside questions about the vitality of the doctrine, it simply does not apply here.[7] The essential facilities doctrine developed in cases in which the defendant controlled a bottleneck feature that prevented a rival from competing in a separate market with a different product or service. (*See* Actelion Br. at 15.) Defendants have not identified a single application of the doctrine in circumstances like those here, where defendants seek access to the essential facilities—Actelion's drug products—for the sole purpose of replicating those same products.

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[7] Defendants cite *Mid-South Grizzlies v. NFL*, 550 F. Supp. 558 (E.D. Pa. 1982), for the proposition that the doctrine only applies where a party is denied access to something which is controlled by its competitors. (Opp. at 41.) While that is a necessary condition, it is not a sufficient one. The doctrine has only been applied where a party controlled a facility in one market that was essential to competition in a separate, different market in which the two parties competed.

See 21 U.S.C. § 355(j)(2)(A)(ii)-(iii) (generic drugs must be shown to be the "same as" the reference listed drug for ANDA approval).

2. Actelion Cannot Be Forced To Sell A Patented Product.

Forcing Actelion to sell its patented products against its wishes would contravene the fundamental rights granted by the patent laws. (*See* Actelion Br. at 16-17.) Defendants claim that Actelion's patent rights are "irrelevant" and deserve "no deference." (Opp. at 42, 43.) Defendants mistakenly contend that the Bolar Amendment, 35 U.S.C. § 271(e)(1), supports this proposition. (*See* Opp. at 7, 26, 42, 44.) The Bolar Amendment, however, simply provides that the use of a patented product to develop and submit information to the FDA is not an act of infringement. But Actelion has never argued that the use of Tracleer or Zavesca samples for bioequivalence testing would infringe its patents. Rather, Actelion has the absolute right under the patent laws to refuse to sell its patented product, and it is that right that is implicated by defendants' counterclaims. 35 U.S.C. § 154(a)(1).[8]

This is the fundamental property right under patent law—the right to determine whether or not to offer a patented invention for sale. A patent holder's right to exclude is "the very essence of the right conferred by the patent." *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 429 (1908). *See also In re Indep. Servs. Org. Antitrust Litig.*, 989 F. Supp. 1131, 1140 (D. Kan. 1997) ("A patent holder's intent in exercising its exclusionary power is irrelevant because the right to exclude competitors from using an invention is expressly authorized by

[8] For this reason, defendants' argument that any issues relating to patent rights are prematurely raised (Opp. at 43-44) rests on the misguided notion that patent rights are implicated only if an act of infringement occurs. This ignores the fundamental right to exclude embodied in the patent laws.

law."), *aff'd*, 203 F.3d 1322 (Fed. Cir. 2000). Use of the essential facilities doctrine to force a patent holder to sell its patented product to a competitor would thus eliminate the very right to exclude that is granted by the patent laws.

This is not a novel issue—courts have recognized that "the antitrust laws do not negate the patentee's right to exclude others from patent property." *Indep. Servs. Org.*, 203 F.3d at 1325 (citation omitted). In *Applera Corp. v. MJ Research, Inc.*, the court explicitly held that finding a patent to be an essential facility to which a patent holder must provide access would "subvert the plain meaning and purpose of the Patent Act." 349 F. Supp. 2d 338, 348 (D. Conn. 2004). The court in *Eatoni Ergonomics, Inc. v. Research in Motion Corp.* likewise held that the essential facilities doctrine did not apply where the facility sought was patented technology "from which [the defendant] derives the lawful power to exclude others' use." 486 F. App'x 186, 190 (2d Cir. 2012). Defendants' attempt to distinguish *Applera* and *Eatoni* by referring to the Bolar Amendment is a non sequitur. The Bolar Amendment did not eliminate a patent holder's right to exclude others or require a patent holder sell its patented product to firms with which it chooses not to deal. [9]

[9] The defendants' citation to *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), is odd and entirely beside the point. That case holds that a patent holder may be stripped of its rights under the patent law if it engaged in knowing and willful fraud on the Patent and Trademark Office. Justice Harlan's concurrence, cited by defendants, was also explicitly limited to a discussion of the application of antitrust law in cases where a patent was obtained by knowing and willful fraud. *See id.* at 179-80. Defendants have not made a single allegation that any one of the Tracleer or Zavesca patents was procured by fraud, so this case is meaningless in the present context.

3. Alternative Routes to Market Show That Tracleer and Zavesca Are Not Essential to Competition.

Defendants mistakenly insist that market entry must be on their terms, through the ANDA shortcut. But defendants admit that if they entered by an alternate pathway, such as an NDA, they "would face immediate competition from Tracleer or Zavesca." (Opp. at 47 n.19.) This concession that an NDA is an alternative pathway to market entry is fatal to their claim that access to Tracleer and Zavesca is essential to competition. *See Monarch Entm't Bureau, Inc. v. N.J. Highway Auth.*, 715 F. Supp. 1290, 1300 (D.N.J. 1989) (a facility is only essential if it is "vital to the claimant's competitive viability").

Alternative means of competing are available to defendants as a matter of law. The pathways to market entry are delineated by the Federal Food, Drug, and Cosmetic Act ("FDCA"), which sets forth multiple avenues for pharmaceutical entry: new drug application ("NDA"), abbreviated new drug application ("ANDA"), and a 505(b)(2) application. *See* 21 U.S.C. § 355. As a matter of law, therefore, the defendants have alternate routes to compete that do not require samples of Actelion's products.

The defendants' summary of the Hatch-Waxman Amendments to the FDCA in their opposition brief is misleading because it ignores these alternate routes. Defendants focus only on one of the pathways—an ANDA—without acknowledging the others. Before the Hatch-Waxman Amendments were enacted, there was basically just one pathway to market, the NDA. Hatch-Waxman created two new statutory pathways for drugs to be approved in the US: the 505(b)(2) NDA and 505(j) ANDA. Hatch-Waxman broadened the number of pathways

available to an applicant. Under Hatch-Waxman, applicants who cannot use the ANDA pathway may use the other pathways to enter.[10]

Defendants argue that they should not have to use an alternate route because it costs more to file an NDA than an ANDA. (Opp. at 47 n.19.) But the law does not require an alternate route to entry to be the most economical, the easiest, or the most lucrative. (Actelion Br. at 17-18.) Competition may require a significant investment of money and time, but this does not make a cheaper pathway an essential facility. *Goldwasser v. Ameritech Corp.* 222 F.3d 390, 399 (7th Cir. 2000) (although duplicating an incumbent's facilities might require a large investment, and take substantial time, such costs did not justify finding that the incumbent's facilities were essential because "this is the normal way in which competitive markets work"). Dozens of companies choose to bring their products to market using the NDA pathway every year, and there is no reason why the defendants could not do so as well.

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[10] The FDA itself clearly contemplates the availability of the 505(b)(1) NDA for a duplicate version of a branded drug. The following question and answer appears in an FDA guide to the drug development process:

> 13. Do the new drug product exclusivity provisions of the Act provide any protection from the marketing of a duplicate version of the same drug product if the duplicate version is the subject of a full new drug application submitted under 505(b)(1) of the Act?
>
> No, the new drug product exclusivity provisions do not provide any protection under these conditions.

FDA, Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity, *available at* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.htm.

D. Neither Hatch-Waxman Nor the REMS Statute Imposes a Duty to Deal.

Nothing in the Hatch-Waxman Amendments creates an obligation to deal or otherwise requires pharmaceutical innovators to hand-deliver samples for bioequivalence testing. Even after Hatch-Waxman, it remains the business decision of the innovator company to choose with whom it does business. Defendants and the *amici* argue that allowing manufacturers of drugs with significant safety issues to exercise their right not to deal with potential generic rivals will undermine the Hatch-Waxman Amendments to the FDCA, through which Congress provided the ANDA shortcut mechanism. *See* 21 U.S.C. § 355(j). But when Congress enacted Hatch-Waxman, it did not require drug innovators to sell their products to ANDA-filers.

Similarly, nothing in the REMS statute or related regulatory scheme requires an innovator company to give up the right to choose with whom to deal, merely because its drug is subject to REMS restrictions. The defendants mistakenly rely on a provision enacted as part of the Food and Drug Administration Amendment Act of 2007 ("FDAAA") that states: "No holder of an approved covered application shall use any element to assure safe use . . . to block or delay approval of an application under section 355(b)(2) or (j) . . . or to prevent application of such element . . . to a drug that is the subject of an [ANDA]." (Apotex Countercl. ¶ 25; Roxane Countercl. ¶ 29; Actavis Countercl. ¶ 26 (citing 21 U.S.C. § 355-1(f)(8))). That provision does not abrogate a company's right to choose with whom it will do business, or create any duty to deal with, or to assist, rival manufacturers.[11]

[11] Moreover, as explained above, Actelion is not actually alleged to have "used" any element to assure safe use in a manner inconsistent with insuring patient safety. Defendants' conclusory argument to the contrary lacks any foundation whatsoever.

Congress considered and rejected an explicit requirement directing branded companies to supply generic competitors. (*See* Actelion Br. at 18-20.) Defendants and *amici* suggest that there might have been a variety of reasons for Congress's rejection of this language, but three things are certain: (1) Congress was aware of this issue; (2) it considered adopting a requirement that branded companies sell REMS products to potential generic applicants; and (3) it did not do so. Defendants and *amici* argue that Actelion's position disturbs the balance struck by Congress in the Hatch-Waxman amendments, but Congress's choice not to enact the legislation described above reflects its judgment about the appropriate balance required between protecting intellectual property, the branded companies' right to choose with whom to do business, potential liability issues, promoting competition, and other related issues. If the defendants, or the *amici*, are unhappy with this balance, the proper place to address this concern is Congress, not the courts.[12]

III. ROXANE'S COUNTERCLAIMS FAIL TO STATE A CLAIM UNDER SECTION 1 OF THE SHERMAN ACT UPON WHICH RELIEF CAN BE GRANTED.

Roxane's Section 1 counterclaims based on Actelion's distribution arrangements fail for several reasons.[13] First, the challenged restrictions merely insure that the distributors comply with the FDA-approved, and *Noerr*-protected, REMS and restricted distribution program, as Actelion is required to do by law. Second, the distribution restrictions required to implement these programs are unilateral conditions that Actelion imposes on its distributors and, therefore,

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[12] Indeed, the Generic Pharmaceutical Association has recently proposed legislation to Congress on this very issue. *See* Letter from Ralph G. Neas, President & CEO, Generic Pharm. Ass'n to John Boehner, Speaker of the House, and Nancy Pelosi, House Minority Leader (Mar. 7, 2013) (attached as Ex. B).

[13] Only Roxane and proposed intervenor Johnson Matthey have attempted to raise a claim under Section 1 of the Sherman Antitrust Act.

they are not subject to Section 1, which requires an agreement. In addition, Actelion and its distributors are not independent economic actors and, as a result, they are not legally capable of conspiring for Section 1 purposes.

To be clear, Actelion is not, as Roxane suggests, asking "this court to be the first one to hold that vertical agreements between a manufacturer and a distributor are *subject to no antitrust scrutiny whatsoever*." (Opp. at 54) (emphasis in original). To the contrary, Actelion's point is merely that, under the specific circumstances alleged in this case, the challenged provisions of its distribution arrangements do not fall within the scope of Section 1 of the Sherman Act as a matter of law.

A. The Unilateral Conditions Imposed By Actelion Are Required to Give Effect to the REMS and Restricted Distribution Program.

The restrictions complained of by Roxane are merely conditions that are necessary to enforce the FDA-reviewed and approved REMS program for Tracleer and restricted distribution for Zavesca. For example, as required by the REMS, certified pharmacies that distribute Tracleer may only dispense Tracleer to patients who are enrolled in the REMS program and who have provided proof that liver function and pregnancy testing were completed. (*See* Tracleer REMS at 4-5.) These restrictions give effect to the REMS components approved by the FDA. (*See* Tracleer Approval Letter at 2.) The distributors are merely acting as Actelion's "arms and legs" in implementing the FDA-reviewed and approved programs, and Actelion is merely insuring that they comply with the conditions set forth in these programs.

Roxane has alleged nothing to the contrary. It has, for example, alleged no fact demonstrating that the restrictions go beyond the plainly legitimate—indeed required—purpose of compliance with the FDA-approved REMS and the restricted distribution programs. Instead,

it simply labels Actelion's distribution agreements "unlawful." (Roxane Countercl. ¶ 181). But these agreements are not merely "pro-competitive," as most vertical agreements are (*see* FTC Br. at 18), they are ***necessary preconditions*** to the safe distribution and use of the drugs. Therefore, the restrictions—which do nothing more than implement the FDA-approved, and *Noerr*-protected, REMS—cannot give rise to antitrust liability as a matter of law. Roxane cannot avoid this fact with a conclusory allegation that Actelion's distribution arrangements are "unlawful." *See Iqbal*, 556 U.S. at 679. Roxane's Section 1 claim fails for this reason alone.

B. The Challenged Restrictions Are Properly Viewed As Unilateral Conditions.

Roxane's Section 1 claim also fails for a related, but independent reason. The restrictions that it challenges are properly viewed as conditions of doing business imposed on specialty distributors ***unilaterally*** by Actelion. As a unilateral action, Actelion's imposition of restrictions for its distributors is not within the scope of Section 1.

A Section 1 claim requires an allegation of an illegal "contract, combination . . ., or conspiracy, in restraint of trade." 15 U.S.C. § 1. Roxane has not pled a contract, combination or conspiracy. The restrictions challenged by Roxane are unilateral conditions imposed by Actelion and required by the drugs' restricted distribution programs.

These types of one-way preconditions to distribution agreements do not fall within the scope of Section 1 because:

> Vertical restraints, like any other business conduct or practice proscribed by Section 1 of the Sherman Act, must meet the statutory requirement of a "contract, combination . . ., or conspiracy, in restraint of trade or commerce." Thus, purely unilateral conduct will not suffice . . . . This is, of course, the famous *Colgate* doctrine, and it is based on the longstanding view that a manufacturer or supplier has an unfettered right to decide with whom it will do business.

J. Thomas Rosch, Comm'r, FTC, *Developments in the Law of Vertical Restraints: 2012* (May 7, 2012), *available at* http://www.ftc.gov/speeches/rosch/120507verticalrestraints.pdf (quoting 15 U.S.C. § 1 and citing *Colgate*, 250 U.S. at 307).

Accepting everything Roxane pleads as true—that as a condition to becoming distributors of Actelion's exclusive product, distributors must adhere to the Tracleer REMS and the restricted distribution program for Zavesca, and that they may not distribute to any non-specialized pharmacy (including generics)—it alleges nothing more than a unilateral condition imposed by Actelion. It is well-settled that a manufacturer may announce the terms under which it will deal, and may deal only with customers which abide by those terms without giving rise to a Section 1 claim. *Colgate*, 250 U.S. at 307.

The holding in *Sambreel Holdings LLC v. Facebook, Inc.*, No. 12-cv-668, 2012 WL 5995240 (S.D. Cal. Nov. 29, 2012), for example, is particularly instructive. In that case, the plaintiff claimed that Facebook's terms of use for application developers prevented them from doing business with other, potentially competing platforms and constituted a group boycott in violation of Section 1. The court dismissed the Section 1 claim, holding that there was no concerted action. According to the court, Facebook's terms of use, although reflected in its agreements with developers, were properly viewed as a condition of doing business unilaterally imposed by Facebook.[14] *Id.* at *4. Similarly, here, Actelion's restrictions on distributors' ability to sell Tracleer and Zavesca outside of the REMS or restricted distribution plan are most appropriately characterized as unilaterally-imposed conditions, not subject to Section 1.

[14] Facebook was represented by Kirkland & Ellis, counsel for Roxane in this case.

C. Actelion's Relationships with Its Distributors Cannot Give Rise to a Section 1 Claim Because They Are Not Independent Economic Actors.

Roxane's Section 1 claim fails for an additional, independent reason. Even if a complaint adequately alleges concerted action, the alleged "contract, combination . . . , or conspiracy" must join together two separate economic actors. *Am. Needle, Inc. v. NFL*, 130 S. Ct. 2201, 2212 (2010); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 769 (1984). Here, Actelion and its distributors are not independent actors with respect to the supply of Tracleer or Zavesca. The distribution arrangements do not remove from the markets a source of competition in the manufacture or distribution of the drugs that would exist in their absence. *See Levi Case Co. v. ATS Prods., Inc.*, 788 F. Supp. 428 (N.D. Cal. 1992); *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. Civ.A 10-1077, 2011 WL 2550835 (D. Del. June 10, 2011). Roxane, by failing to plead any facts to the contrary, has failed to state a claim under Section 1.

Roxane incorrectly states that "no federal court has ever issued such a holding" that companies that are "not independent sources of economic power . . . are not legally capable of conspiring for antitrust purposes." (Opp. at 53) (internal quotation marks removed). Roxane also wildly overstates what would result if *Copperweld*'s principles were applied in this case, claiming that "this court [would] be the first one to hold that vertical agreements between a manufacturer and a distributor are *subject to no antitrust scrutiny whatsoever*." (Opp. at 54) (emphasis in original). Roxane is wrong on both points, as evidenced by the holdings in federal cases such as *Levi Case* and *Shionogi*.[15]

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[15] Roxane's authority on this point is not to the contrary, and stands for nothing more than the proposition that certain "vertical agreements between a manufacturer and a distributor" can be subject to the rule of reason test. Actelion does not disagree, but this proposition does not apply to the particular arrangements at issue in this case.

IV. DEFENDANTS DO NOT STATE A CLAIM FOR TORTIOUS INTERFERENCE.

As with their antitrust counterclaims, defendants have not alleged facts that make their tortious interference counterclaims plausible.

In New Jersey, tortious interference requires allegations of malice—impropriety in dealing such as physical violence, misrepresentations, abuse of legal process, unlawful conduct, or unwarranted economic pressure. *DiGiorgio Corp. v. Mendez & Co.*, 230 F. Supp. 2d 552, 565 (D.N.J. 2002). Defendants have not alleged any facts that support this element of the claim. Defendants' new argument alleging a "multi-pronged scheme" that was "unlawful" (*see* Opp. at 57) is nothing more than defendants' proffered legal conclusion which is insufficient to survive a motion to dismiss. *Iqbal*, 556 U.S. at 678; *see also* Part I, *supra*.

As set forth above, Actelion has at all times acted lawfully. Actelion has the right to refuse to deal with defendants. Where, as here, allegations do not plausibly demonstrate that a party acted out of malice, a claim for tortious interference fails on the pleadings. *See, e.g.*, *Marin v. Landgraf*, No. 11-690, 2013 WL 356623, at *5 (D.N.J. Jan. 29, 2013) (dismissing claim that lacked "factual underpinnings"); *Johnson & Johnson v. Guidant Corp.*, 525 F. Supp. 2d 336, 361-62 (S.D.N.Y. 2007) (dismissing claim that lacked factual allegations of illicit conduct) (applying New Jersey law).

CONCLUSION

For the foregoing reasons, Actelion's motion for judgment on the pleadings and to dismiss the counterclaims should be granted.

March 22, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of March, 2013, I caused a true and correct copy of the foregoing Reply Memorandum of Law in Support of Plaintiffs' Motion for Judgment on the Pleadings and to Dismiss the Counterclaims to be served via the Court's ECF system on all counsel of record.

/s Michelle Hart Yeary

Michelle Hart Yeary